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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,030	06/29/2006	Krishna Murthy Ella	06-40104-US	7696

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EXAMINER
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BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

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09/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,030	<b>Applicant(s)</b> ELLA ET AL.	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 3-9, 11 and 14-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Appendix A</u> .                       |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of invention I with the required species in the reply filed on June 13, 2008 is acknowledged. The traversal is on the ground(s) that the examiner must show that a serious burden exists if the species were not searched by individually and that claims 2-4, 6, 11 and 16 recite a reasonable number of species and therefore these species can be searched without a serious burden. This is not found persuasive because even though the number of different cell types, or protein recovery methods are small, a serious search burden does exist as evidenced by a word search in NCBI-Pubmed (see Appendix A). For example, using the terms yeast and vector, 122 citations were found, while broadly focusing on eukaryotes and vector, 3126 citations were found, and lastly, searching based on prokaryotes and vector, 33,650 citations were found. Similar results were seen for searches done based on the species of groups 'B.' and 'D.'. Therefore, if all three cells were considered on claim 3, over 36,000 documents would have to be considered. That is therefore considered a serious search burden. However, upon further consideration the species election for groups C. and E. have been withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10, 12 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 13, 2008.

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***Claim Objections***

Claims 3-9, 11 and 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependent claim (see claims 3-5, 8, 9 and 14-16) and multiple dependent claims must refer to claims in the alternative (see claim 3), and claims 6 and 11 are objected to since they depend from improper multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 1 and 2 are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "...that the purification is carried out by a novel technique termed as HIMAX technology which is as herein described...", however, the claimed process does not recite any active steps, therefore, it is not clear how the preparation and purification of proteins carried out.

The claimed invention is drawn to a process for the preparation and purification of protein(s) such as viral antigenic proteins, other recombinant therapeutic proteins characterized in that the purification is carried out by a novel technique termed as HIMAX technology which is as herein described and recovering the said protein(s). However, applicants do not provide any active steps that describe to one skilled in the art how to use the claimed "HIMAX technology".

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Even though the specification can be used for guidance on claim interpretation, when an essential limitation or limitations are not present in the claims ambiguity exists with regard to the intended invention. Furthermore, the MPEP states in section 2106 (II)(C), “While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not itself impose that limitation.”. The claims are rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

- (a) the vector cells are subjected to lysis in the absence of a detergent to obtain a cell lysate;
- (b) subjecting the cell lysate of steps as to centrifugation ranging from 1000g to 10,000g;
- (c) obtaining a solid from step (b) by decantation wherein the said solid comprising the said proteins;
- (d) suspending the said solid in a buffer of pH 6 to 7.5 and optimally treating this with a detergent to solubilize the minute impurities if any;
- (e) as a part of HIMAX technology, the said protein(s) is/are captured by the addition of divalent ionic salt having concentration ranging from 0.2% to 10% with counter ions of either phosphate, chloride and/or acetate solution to form an insoluble matrix.
- (f) subjecting the said insoluble matrix for centrifugation optimally to form pellets;

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(g) subjecting repeated desorptions process to release the bound antigen from insoluble matrix/pellets by using either Tris buffer of pH 8.0 to 8.5 or Tris buffer with EDTA at pH 7.0 to 8.0;

(h) finally, recovering the said proteins through ultrafiltration, chromatography on colloidal silica, hydrophobic and or affinity chromatography, ion exchange, diafiltration, sterile filtration or a combination thereof.

Regarding claim 2, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Summary***

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648